## REMARKS

In the Final office action mailed February 9, 2007, claims 1-39, 41-50 and 81-101 were pending. Claims 6, 7, 10-12, 16, 17, 22-26, 30, 33, 39, 41-44 and 49-50 were withdrawn as being directed to a non-elected invention. Claims 81-101 have been allowed, and claim 21 was objected to but indicated to be allowable if rewritten in independent form incorporating the base claim and any intervening claims. Claims 1-5, 8, 9- 13-15, 18-20, 27-29, 31, 32, 34-38 and 45-48 stand rejected. In this response, claims 90 and 91 have been amended, and claims 102-105 have been added. Reconsideration of the present application as amended and including claims 1-39, 41-50 and 81-105 is respectfully requested.

Claim 90 was objected to for an informality. Claim 90 has been amended as suggested in the office action. Withdrawal of the objection to claim 90 is respectfully requested.

Claim 91 was rejected under 35 USC §112, second paragraph since "said thickness" in line 1 lacked antecedent basis. Claim 90 has been amended to replace "said thickness" with "said enlarged mid-portion", which finds antecedent basis in claim 90. Withdrawal of the rejection of claim 91 is respectfully requested.

Claims 1-3, 5, 8, 9, 13, 14, 18-20, 27-29, 32, 34-37 and 45-44 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,440,169 to Elberg et al. Elberg discloses an interspinous stabilizer with anchor members 2 to anchor it to the spinous processes of adjacent vertebrae. Elberg discloses that the stabilizer has a body 6 that "can be compressed in the direction 5 by a force tending to move the two processes towards each other. As shown in the figure, the body 6 has been compressed from a particular starting configuration. When the load is removed, the body 6 reverts spontaneously to its starting configuration." See col. 3, lines 31-36. Elberg further discloses that the body is arranged so that the body is "compressible in the alignment direction, and from a given configuration by the application of a force, the body being adapted to revert to the given configuration spontaneously after the force is removed." See col. 1, lines 54-57. Accordingly, Elberg discloses a device that is attached to spinous processes in a starting configuration and is thereafter compressed by spinal forces, and reverts to the starting configuration when the spinal forces are removed.

Furthermore, Elberg et al. discloses that the device has ends specifically configured to receive a spinous process. For example, anchor members 2 in Figures 1-6 are U-shaped

members with a pair of jaws that are clamped around the respective spinous process. See col. 4, lines 57-62. In one embodiment, anchor member 2 includes passages 27 "for inserting a tool for maneuvering the jaws...." See col. 4, lines 49-50. The arrangement between body 6 and anchors 2 allows "members 2 to rotate relative to each other about a rotation point passing through the direction 5. By applying an appropriate force they can therefore be given a temporary relative inclination, the members 3 becoming parallel to each other again when the force is removed." See col. 3, lines 36-40. Accordingly, Elberg et al. only discloses a device that is for attachment to the spinous processes, and there is no disclosure of any holes or structure in the device for receiving anchors or that allow the device to be attached to any other portion of the vertebrae that is along a concavely curved surface or side of the spinal column.

Claim 1 recites structural features associated with the implant that maintain separation of the adjacent vertebrae and distract the spinal column segment when attached thereto. Claim 1 recites "a body including first and second ends along a longitudinal axis spaced by a length sized for attachment to respective ones of first and second vertebrae along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment, said body being structured with said length further sized so that said body maintains separation of the first and second vertebrae when attached to the first and second vertebrae to distract the spinal column segment along the concavely curved surface toward a straightened configuration while permitting motion of the spinal column segment when attached to the first and second vertebrae." Elberg fails to disclose, among other features, a body with a length sized to maintain separation of the first and second vertebrae when attached thereto to distract the spinal column segment while permitting motion of the spinal column segment. There is no disclosure in Elberg that the device provides distraction at all. Rather, the device in Elberg includes a length relative to the bone section sized to maintain a spacing between the bone portion and compress in response to force applied by the spinous processes and revert to the starting configuration when the force is removed. In addition, the arrangement between body 6 and anchor members 2 is structured for attachment to spinous processes, and there is no disclosure that the device is structured for attachment to "first and second vertebrae along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment" as recited in

claim 1. Accordingly, Elberg fails to disclose the elements recited in claim 1, and withdrawal of this basis of the rejection of claim 1 is respectfully requested.

Claims 2-3, 5, 8, 9, 13, 14, 18-20 depending from claim 1 were also rejected as being anticipated by Elberg. These claims are believed to distinguish Elberg at least for the reasons claim 1 distinguishes Elberg, and for other reasons. For example, claim 5 recites "wherein said first end of said body includes a first hole for receiving a first bone anchor engageable to the first vertebra and said second end includes a second hole for receiving a second bone anchor engageable to the second vertebra." As discussed above, passages 27 are for receiving a manipulation tool, and are located relative to the spinous process such that an anchor positioned in the passage could not engage the device to the spinous process. Withdrawal of this basis of the rejection of claims 2-3, 5, 8, 9, 13, 14, 18-20 depending from claim 1 is respectfully requested.

Claim 27 recites structural features associated with the implant that distract vertebrae when attached to the vertebrae. Claim 27 recites "a body with a length along a longitudinal axis extending between opposite ends when said body is in a first condition, said body including a second condition wherein said body is longitudinally compressed between said opposite ends with said compressed length sized for implanting said body between the first and second vertebrae, said body including means for reforming from said second condition toward said length of said first condition when implanted and released from said compression to exert a distractive force between the first and second vertebrae and permit relative motion between the first and second vertebrae." Elberg fails to disclose the features recited in claim 27. Rather, the device in Elberg is implanted in a starting configuration with no loading so that the U-shaped ends are spaced to receive the respective spinous processes. When the ends are attached to the spinous processes, there is no distraction or other loading on the spinous processes. Accordingly, withdrawal of this basis of the rejection of claim 27 is respectfully requested.

Claims 28, 29, 32, 34-37 depending from claim 27 were also rejected as being anticipated by Elberg. These claims distinguish Elberg at least for the reasons claim 27 distinguishes Elberg and for other reasons. For example, claim 32 recites "wherein said body includes a lower surface positionable adjacent the first and second vertebrae and a base portion along said lower surface having a substantially constant thickness along said body, said body further including an upper

portion extending from said base portion and including said enlarged mid-portion, said upper portion including a thickness between said base portion and an upper surface of said body, said thickness varying along a length of said upper portion of said body." The Final Office Action does not provide any indication of how this arrangement of the thickness of the base portion and upper portion is disclosed in Elberg. Withdrawal of this basis of the rejection of these claims depending from claim 27 is respectfully requested.

Claim 45 recites the structural features associated with the implant that distract vertebrae when attached to the vertebrae. Claim 45 recites a first anchor and a second anchor and "a body positionable along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment and including a length between opposite first and second ends sized for attachment to said first and second anchors, said body being structured with said opposite ends biased away from one another against said first and second anchors to distract the spinal column segment along the concavely curved surface and between the first and second anchors toward a straightened configuration while permitting motion of the spinal column segment when attached to the first and second vertebrae." As discussed above with respect to claim 1, Elberg fails to disclose, among other features, a body with first and second ends spaced by a length sized for attachment to first and second vertebrae. Elberg also fails to disclose or suggest a body structured with opposite ends biased away form one another to distract a spinal column segment along a concavely curved surface of the spinal column segment. Rather, the device in Elberg includes a length relative to the bone section sized to maintain a spacing between the bone portion and compress in response to force applied by the spinous processes and revert to the starting configuration when the force is removed. In addition, the arrangement between body 6 and anchor members 2 is structured for attachment to spinous processes, and there is no disclosure that the device is structured so that it is "positionable along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment" as recited in claim 45. Accordingly, Elberg fails to disclose the elements recited in claim 45, and withdrawal of this basis of the rejection of claim 45 is respectfully requested.

Claims 46-48 depending from claim 45 were also rejected as being anticipated by Elberg. These claims are believed to distinguish Elberg at least for the reasons claim 45

distinguishes Elberg, and withdrawal of this basis of the rejection of these claims is respectfully requested.

Claims 1-5, 8-9, 13-15, 18, 27-29, 31, 37-38 and 45-48 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,019,793 to Perren et al. Perren discloses a prosthetic device that is adapted for placement between two adjoining vertebrae for a partial or total disc replacement. The device has an upper plate and a lower plate (plates 1) interconnected with connecting means 4. The spacing between the plates is sizes to contact the endplates of the adjacent vertebrae. The device is made from a shape memory alloy so that it can be rolled into a cylindrical configuration for insertion at a temperature below the transition temperature and thereafter changed to a rectangular configuration with a temperature above the transition temperature. See col. 1, lines 36-44. The device is structured so that after reaching the transition temperature it has "a predetermined configuration suitable to its spacing function" which is "designed to provide optimal spacing function for the two adjacent vertebrae." See col. 1, lines 62-65. There is no disclosure that the device is configured or otherwise structured to distract the adjacent vertebrae, includes a length or other configuration suitable for positioning along a concavely curved surface or portion of the spine, or includes ends attachable to first and second vertebrae.

Claim 1, in contrast, recites structural features associated with the implant that maintain separation of the adjacent vertebrae and distract the spinal column segment when attached thereto. Perren fails to disclose, among other features, "a body including first and second ends along a longitudinal axis spaced by a length sized for attachment to respective ones of first and second vertebrae along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment" as recited in claim 1. In contrast, the device in Perren is sized to engage adjacent vertebral endplates in a spinal disc space. Perren also fails to disclose "said body being structured with said length further sized so that said body maintains separation of the first and second vertebrae when attached to the first and second vertebrae to distract the spinal column segment along the concavely curved surface toward a straightened configuration while permitting motion of the spinal column segment when attached to the first and second vertebrae." There is no disclosure that the device in Perren distracts or is structured to distract vertebrae. Rather, Perren only discloses the device capable of changing shape from a first

configuration for insertion endoscopically and thereafter changing shape in response to a temperature change to maintain a spacing between the vertebrae. There is no disclosure that this change in shape distracts the vertebrae, or that the device is otherwise configured to distract vertebrae along a concavely curved surface of a spinal column segment. Accordingly, Perren fails to disclose the elements recited in claim 1, and withdrawal of this basis of the rejection of claim 1 is respectfully requested.

Claims 2-5, 8-9, 13-15 and 18 depending from claim 1 were also rejected as being anticipated by Perren. These claims are believed to distinguish Perren at least for the reasons claim 1 distinguishes Perren and for other reasons. For example, claim 5 recites "wherein said first end of said body includes a first hole for receiving a first bone anchor engageable to the first vertebra and said second end includes a second hole for receiving a second bone anchor engageable to the second vertebra." Holes 5 in the plates 1 are for receiving bone growth, and there is no disclosure that the holes are for receiving bone anchors. Claim 13 recites "wherein said body includes a lower surface directed towards the spinal column segment when said body is attached thereto, said body further including an upper surface opposite said lower surface." There is no disclosure nor has the Final Office Action indicated where Perren discloses the device includes any lower surface directed toward the spinal column segment when the body is attached to the spinal column segment. Claims 14 and 15 depend from claim 13 and recites features directed to the enlarged mid-portion between the upper and lower surface which also are not disclosed in Perren. Accordingly, withdrawal of this basis of the rejection of these claims depending from claim 1 is respectfully requested.

Claim 27 recites structural features associated with the implant that distract vertebrae when attached thereto. Claims 27 recites "said body including means for reforming from said second condition toward said length of said first condition when implanted and released from said compression to exert a distractive force between the first and second vertebrae and permit relative motion between the first and second vertebrae." As discussed above, Perren discloses a device in the disc space that does not distract the vertebrae when attached thereto, but rather maintains a spacing between vertebrae. Claim 27 also recites "a body with a length along a longitudinal axis extending between opposite first and second ends when said body is in a first condition, said body including a second condition wherein said body is longitudinally

compressed between said opposite ends with said compressed length sized for implanting said body between the first and second vertebrae". Perren discloses only that the upper and lower plates are engaged to the endplates of the adjacent vertebrae after the device has transitioned. Since these features in claim 27 are not disclosed in Perren, withdrawal of this basis of the rejection of claim 27 is respectfully requested.

Claims 31, 37 and 38 depending from claim 27 were also rejected as being anticipated by Perren. These claims are believed to distinguish Perren at least for the reasons claim 27 distinguishes Perren and for other reasons. For example, claim 31 recites "wherein said enlarged mid-portion includes a pyramidal shape." Perren does not disclose this feature nor has the Final Office Action indicated where this feature is disclosed in Perren. Accordingly, withdrawal of this basis for rejecting these claims depending from claim 27 is respectfully requested.

Claim 45 recites structural features associated with the implant that distract vertebrae when attached thereto. Claim 45 recites "a first anchor engageable to a first vertebra; a second anchor engageable to a second vertebra; and a body positionable along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment" and that the body includes "a length between opposite first and second ends sized for attachment to said first and second anchors...." As discussed above, Perren fails to disclose any anchors, and further lacks any disclosure of a body positionable along concavely curved surfaces of the spinal column between the anchors. Claim 45 also recites that the body is "structured with said opposite ends biased away from one another against said first and second anchors to distract the spinal column segment along the concavely curved surface and between the first and second anchors toward a straightened configuration while permitting motion of the spinal column segment when attached to the first and second vertebrae." As discussed above, Perren lacks any disclosure that the device therein distracts the vertebrae, and further does not disclose that device includes opposite ends biased away from one another against any anchors to distract the spinal column segment. Still further, Perren does not disclose that the device permits motion of the spinal column segment when attached to the vertebrae. Accordingly, withdrawal of this basis of the rejection of claim 45 is respectfully requested.

Claims 46-48 depending from claim 45 were also rejected as being anticipated by Perren, and these claims distinguish Perren at least for the reasons claim 45 distinguishes Perren and for

other reasons. For example, claim 46 recites "wherein said body is attachable to respective ones of the first and second vertebrae of the spinal column segment with respective ones of the first and second anchors, said body being formable from a first condition to a second condition, wherein said body is formed to said second condition for attachment to the first and second vertebrae and reforms toward said first condition from said second condition to continuously distract the first and second vertebrae." As discussed above, Perren fails to disclose a device attachable to vertebrae with anchor or a device that continuously distracts the vertebrae when attached thereto. Accordingly, withdrawal of this basis of the rejection of claims 46-48 depending from claim 45 is respectfully requested.

Claims 1-5, 8-9, 13, 14, 18-20, 27-29, 34-38 and 45-48 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,293,949 to Justis et al. Justis discloses a spinal stabilization system 20 with an elongate member 22 attachable to vertebrae that is flexible and is comprised of shape memory material that transforms as a result of stress being applied thereto to elongate or shorten and allow spinal motion and then transforms back to the initial configuration when the stress is removed to maintain a desired spacing between vertebrae. See, e.g., col. 2, lines 36-41 and lines 50-59 and col. 6, lines 47-65. The longitudinal member is configured so that when implanted and subjected to stress it shortens or lengthens from its implanted configuration to accommodate motion of the spinal column segment and reforms toward its initial configuration when the stress is released to maintain the spacing between vertebrae, even when the member is prestressed when implanted. See col. 6, line 65 to col. 7, 4 and col. 12, lines 34-37, for example.

Claim 1, in contrast, recites structural features associated with the implant that maintain separation of the adjacent vertebrae and distract the spinal column segment when attached thereto. Claim 1 recites "a body including first and second ends along a longitudinal axis spaced by a length sized for attachment to respective ones of first and second vertebrae along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment, said body being structured with said length further sized so that said body maintains separation of the first and second vertebrae when attached to the first and second vertebrae to distract the spinal column segment along the concavely curved surface toward a straightened configuration while permitting motion of the spinal column segment when attached to the first

and second vertebrae." Justis fails to disclose, among other features, a body with a length sized for attachment to vertebrae of a concavely curved surface of the spine. Justis also fails to disclose or suggest a body with a length sized to maintain separation of the first and second vertebrae when attached thereto to distract the spinal column segment while permitting motion of the spinal column segment. Rather, the member in Justis includes a length relative to the vertebrae sized to maintain the vertebrae in a restorative position when stress is released from the longitudinal member. The longitudinal member shortens or lengthens in response to stress, but when the stress from the vertebrae is removed the device maintains its restorative length between the vertebrae. Accordingly, Justis fails to disclose the elements recited in claim 1, and withdrawal of this basis of the rejection of claim 1 is respectfully requested.

Claims 2-5, 8-9, 13, 14 and 18-20 depending from claim 1 were also rejected as being anticipated by Justis. These claims are believed to distinguish Justis at least for the reasons claim 1 distinguishes Justis, and withdrawal of the rejection of these claims is respectfully requested.

Claim 27 recites structural features associated with the implant that distract vertebrae when attached thereto. Claim 27 recites "a body with a length along a longitudinal axis extending between opposite first and second ends when said body is in a first condition, said body including a second condition wherein said body is longitudinally compressed between said opposite ends with said compressed length sized for implanting said body between the first and second vertebrae, said body including means for reforming from said second condition toward said length of said first condition when implanted and released from said compression to exert a distractive force between the first and second vertebrae and permit relative motion between the first and second vertebrae." Justis discloses pre-stressing the plate to initially transform a portion of the SMA material from austenite to SIM so that the member will never attain an entirely austenitic state when the stress imposed by the vertebrae is removed. When the member is compressed or elongated as a result of stress imposed by the vertebrae, the shape memory material recovers toward the implanted configuration when the stress from the vertebrae is removed to maintain the spacing between the vertebrae. However, there is no disclosure that the member reforms from a compressed length toward a length in a first condition to exert a

distractive force between the vertebrae when implanted. Accordingly, withdrawal of this basis of the rejection of claim 27 is respectfully requested.

Claims 28-29 and 34-38 depending from claim 27 were also rejected as being anticipated by Justis. These claims are believed to distinguish Justis at least for the reasons claim 27 distinguishes Justis and for other reasons. For example, claim 34 depends from claim 32, and claim 32 was not rejected as being anticipated by Justis. Therefore, claim 34 distinguishes Justis at least for the reasons claim 32 was considered to distinguish Justis. Withdrawal of this basis of the rejection of these claims depending from claim 27 is respectfully requested.

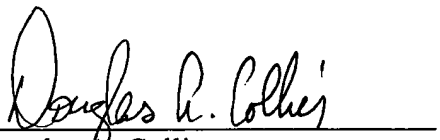
Claim 45 recites the structural features associated with the implant that distract vertebrae when attached to the vertebrae. Claim 45 recites a first anchor and a second anchor and "a body positionable along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment and including a length between opposite first and second ends sized for attachment to said first and second anchors, said body being structured with said opposite ends biased away from one another against said first and second anchors to distract the spinal column segment along the concavely curved surface and between the first and second anchors toward a straightened configuration while permitting motion of the spinal column segment when attached to the first and second vertebrae." As discussed above with respect to claim 27, Justis fails to disclose, among other features, a body structured with opposite ends biased away form one another to distract a spinal column segment along a concavely curved surface of the spinal column segment. In addition, there is no disclosure that the device is structured so that it is "positionable along surfaces of the first and second vertebrae comprising a concavely curved surface of the spinal column segment" as recited in claim 45. Accordingly, Justis fails to disclose the elements recited in claim 45, and withdrawal of this basis of the rejection of claim 45 is respectfully requested.

Claims 46-48 depending from claim 45 were also rejected as being anticipated by Justis. These claims are believed to distinguish Justis at least for the reasons claim 45 distinguishes Justis, and withdrawal of this basis of the rejection of these claims is respectfully requested.

New claims 102-105 have been added in this response and depend from base claims 81 or 90. New claims 102-105 are allowable along with the claims from which each depends.

Reconsideration of the present application as amended and including claims 1-39, 41-50 and 81-105 is respectfully requested. Action toward a Notice of Allowance is hereby solicited. The Examine is encouraged to contact the undersigned to resolve any outstanding issues with regard to the present application.

Respectfully submitted,

By: 

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